K010206

MAR 1 6 2001

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name:	Richard M. Vaught Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101
Date of Preparation:	January 22, 2001
Name of Product:	Dade Behring Dimension® Enzymatic Carbonate (ECO2) Flex® reagent cartridge method
FDA Classification Name:	Bicarbonate/carbon dioxide test system
Predicate Device:	Dade Behring Dimension® Carbon Dioxide method (TCO2)
Device Description:	The Dade Behring Dimension® Enzymatic Carbonate (ECO2) Flex® method is an *in vitro* diagnostic device that consists of prepackaged reagents in a flexible, plastic cartridge (Flex®) for use only on the Dimension® clinical chemistry system.
Intended Use:	The Dimension® ECO2 Flex® method is an *in vitro* diagnostic device intended for the quantitative determination of total carbon dioxide in serum and heparinized plasma.
Comparison to Predicate Device:	The Dimension® ECO2 Flex® method is substantially equivalent to other total carbon dioxide methods, such as the Dimension® TCO2 Severinghaus electrochemical (pH) method. A comparison of the features for these products is provided in the following chart:

Feature	Dade Behring Dimension® ECO2 (Flex®)	Dade Behring Dimension® TCO2 (Electrode)
Intended Use	*in vitro* use, quantitative, total CO2 in serum/plasma	*in vitro* use, quantitative, total CO2 in serum/plasma
Sample type	Serum/heparinized plasma	Serum/heparinized plasma
Assay Range	5 - 45 mmol/L	5 - 45 mmol/L
Assay Time (nominal)	~ 5 minutes	~ 5 minutes
Reaction temperature	37° C	18-29° C (ambient)
Sample Volume	5 uL	45 uL
Principle of Measurement	Bichromatic rate, 405 nm & 700 nm	Electrochemical
Type	Enzymatic endpoint	pH rate measurement

Comments on Substantial Equivalence: Method split sample comparisons between the Dade Behring Dimension® ECO2 and TCO2 methods for measurement of total carbon dioxide gave a correlation coefficient of 0.993, slope of 0.994, and an intercept of 1.6 mmol/L when tested with 267 clinical patient samples.

Conclusion: Based on these split sample comparisons, the Dimension® ECO2 Flex® method is substantially equivalent in principle and performance to other commercially available total carbon dioxide test systems, such as the Dimension® TCO2 method.

R M Vaught

Richard M. Vaught
Regulatory Affairs and Compliance Manager
Date: January 22, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: K010206
Trade Name: Dimension® Enzymatic Carbonate (ECO2) Flex® reagent cartridge method
Regulatory Class: II
Product Code: KHS
Dated: February 27, 2001
Received: February 28, 2001

Dear Mr. Vaught:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Device Name:

Dimension® Enzymatic Carbonate (ECO2) Flex® reagent cartridge method

Indications for Use:

The Dade Behring Dimension® Enzymatic Carbonate(ECO2) Flex® reagent cartridge method is an *in vitro* diagnostic device intended for the quantitative determination of total carbon dioxide in serum and heparinized plasma. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Richard M. Vaught
Regulatory Affairs and Compliance Manager

January 22, 2001

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010206

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)